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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/034,292

Applicant(s)

CLEVELAND ET AL.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. However, application no. 09/260,743 has been abandoned since April 11, 2001, prior to the filing of the instant application. Accordingly, the effective filing date of the instant application is the filing date of the application, i.e., **January 3, 2002**. It is noted that while a Petition to Revive the '743 application has been filed, that Petition has not been granted.

### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

- a) it claims benefit under 35 U.S.C. 119(e) to a non-provisional application (US application no. 09/260,743), and further identifies that non-provisional application as a "provisional application"; and
- b) it claims priority benefit of a non-provisional U.S. application (09/260,743) with which the instant application was not co-pending (see also paragraph 1, above).

***Specification***

3. The disclosure is objected to because of the following informalities: the first line of the specification states that the instant application is a CIP of and claims benefit under 35 U.S.C. 120 of a non-provisional U.S. application (09/260,743) with which the instant application was not co-pending. See also paragraph 1, above.

Appropriate correction is required.

4. The use of the trademarks Pur-Wraps® (see, e.g., page 24) and SORB-IT® (see, e.g., page 26) has been noted in this application. These trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

***Claim Objections***

5. Claims 17-20 are objected to because of the following informalities: in independent claim 17, "desiccant" is misspelled "dessicant." Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are indefinite over the recitation of the limitation “the sealed sample pouch” in claim 1, step (d). There is insufficient antecedent basis for this limitation in the claims. This rejection could be overcome by amending claim 1, step (c), to recite, e.g., “sealing the storage card into a sample pouch, thereby producing a sealed sample pouch.”

Claims 1-16 are indefinite over the recitation of the phrase “storing....in a location designated by the individual or the subject” in claim 1, step (d), in claim 13, step (c), and in claim 15, step (k). It is unclear as to how this recitation is intended to limit the claims. Particularly, is it unclear as to whether this language is intended to require a practitioner to, e.g., place the pouch/folder in a location that has been previously labeled or marked in some manner as a storage location by the individual or subject, whether the claims are intended to encompass mentally “designating” a location for storage, whether any location in which the pouch/folder is placed by the individual/subject would be considered “designated” by the individual/subject, etc. Accordingly, it is unclear as to what actual method steps are required in order to meet the requirements of the claims.

Claim 4 is indefinite over the recitation of the phrase “wherein the sample comprises genetic material selected from the group consisting of viruses and infectious organisms.” First, this recitation is unclear because “viruses and infectious organisms” are types of infectious agents, but not types of “genetic material.” Second, it is unclear as to whether applicants intent was to require a sample that further comprises “genetic material selected from the group consisting of viruses and infectious organisms” in addition to “saliva, mouth cells, or a combination thereof,” whether applicants’ intent was

Art Unit: 1634

to, e.g., further limit the “mouth cells” of claim 3 to “viruses” or “infectious organisms,” etc. This rejection could be overcome by amending the claim to recite, e.g., “wherein the sample further comprises genetic material selected from the group consisting of viral genetic material and genetic material from infectious organisms.”

Claim 6 is indefinite over the recitation of the limitation “the non-blood genetic material.” While there is antecedent basis in the claims for a “non-blood genetic material sample,” there is insufficient antecedent basis for the term “non-blood genetic material” alone. It is unclear as to whether applicants’ intent was to refer to the previously recited “non-blood genetic material sample,” to refer to non-blood genetic material contained in the sample, to refer to non-blood genetic material in general, etc. This rejection could be overcome by amending the claim to recite, e.g., “...degradation of the non-blood genetic material sample,” “...degradation of non-blood genetic material,” etc.

Claim 9 is indefinite over the recitation of the limitations “the absorbent material,” “the sample sorbed thereon,” “the specimen circle,” and “the labeled dry solid support matrix” in step (a). There is insufficient antecedent basis for these limitations in the claims. It appears that claim 9 may have been intended to depend from, e.g., claim 7 or claim 8, rather than claim 1. Clarification is required.

Claim 9 is indefinite over the recitation of the limitation “the affixed sample” in step (b). There is insufficient antecedent basis for this limitation in the claims. This rejection could be overcome by, e.g., amending step (a) of claim 9 to recite “...wherein the sample is affixed to the dry solid support matrix, thereby producing an affixed sample.”

Claims 10-12 are indefinite over the recitation of the term “the storage pouch” and of the phrase “wherein sealing the storage pouch comprises” in claim 10. First, there is insufficient antecedent basis in the claims for the limitation “the storage pouch.” While claim 1 refers to a “sample pouch” and a “sealed sample pouch,” the claim does not recite a “storage pouch.” Further, the recitation “wherein sealing the storage pouch comprises” is unclear, as claim 1 does not include a step of “sealing a storage pouch.” Rather, claim 1 includes steps of “sealing the storage card into a sample pouch” and “storing the sealed sample pouch.” As claim 1 does not include a step of “sealing the storage pouch,” it is unclear as to how claims 10-12 are intended to limit the method of claim 1. The claims should be amended so as to make clear how claims 10-12 relate back to and further limit the method of claim 1.

Claims 10-12 are indefinite over the recitation of the limitations “the dry solid matrix,” “the sample affixed to the dry solid matrix,” and “the storage card containing the sample affixed to the dry solid matrix” in claim 10, step (b). There is insufficient antecedent basis for these limitations in the claims. It appears that claim 10 may have been intended to depend from, e.g., claim 9, which recites a step in which a sample is affixed to the “dry solid support matrix.” Regarding the recitation “the dry solid matrix,” it is noted that while claim 1 does refer to a “dry solid support matrix,” the term “dry solid matrix” is not employed in the claim.

Claims 10-12 are indefinite over the recitation of the limitation “the closed portion of the storage pouch” in claim 10, step (d). First, there is insufficient antecedent basis for this limitation in the claims, as the claims do not previously refer to or describe a

Art Unit: 1634

“closed portion of the storage pouch.” Second, as claim 10, step (c), recites a step of “closing the storage pouch,” it is unclear as to what might constitute “the closed portion” of such a pouch. For example, is the claim intended to require a pouch having multiple sections in which one section is open and one is closed (and thereby constitutes a “closed portion”)? Clarification is required in order to apprise one of skill in the art as to what actual steps or actions would be encompassed by the limitation “placing a tape over the closed portion of the storage pouch.”

Claims 12, 15-16, and 20 are indefinite over the recitation of the term “tamper-resistant security tape” in claims 12, 15, and 20, because it is unclear as to how this recitation is intended to further limit the claims. While types of tape having particular features that improve security and/or tamper-resistance are known in the art (e.g., the “tamper indicating packaging tape” of Haas et al [U.S. Patent No. 5,862,101], as discussed below), the art also teaches that the use of any type of tape improves security and aids in resistance to tampering (see, e.g., the teachings of Turner [U.S. Patent No. 5,211,286], as discussed below). As neither the specification nor the art provide a clear and limiting definition for the term “tamper-resistant security tape,” it is unclear as to whether this recitation is intended to limit the claims to a type of tape having, e.g., particular structural features that would distinguish it from other types of tape (and if so, what particular features would be required in order for a tape to be considered “tamper resistant security tape”). Thus, the recitation “tamper-resistant security tape” does not apprise one of skill in the art as to the metes and bounds of the claimed invention.



Claims 13 and 15-20 are indefinite over the recitation of the terms “permanent storage folder” and “permanent storage record folder” in claims 13, 15 and 17. While the specification discusses particular types of storage folders (e.g., a “water-resistant, puncture-resistant permanent storage folder;” see page 26 of the specification), and while types of file folders having particular structural features that are designed for storage of permanent information are known in the art (e.g., the multi-section file folder of Biddle et al [U.S. Patent No. 5,492,268], as discussed below), it is also a property of any type of folder that it may be employed in the permanent storage of records and other materials. As neither the specification nor the art provide a clear and limiting definition for the term “permanent storage folder” and “permanent storage record folder,” it is unclear as to whether this recitation is intended to limit the claims to a type of folder having, e.g., particular structural features that would distinguish it from other types of folders (and if so, what particular features would be required in order for a folder to be considered a “permanent storage folder” or a “permanent storage record folder”). Thus, the recitation “permanent storage folder”/“permanent storage record folder” does not apprise one of skill in the art as to the metes and bounds of the claimed invention.

Claim 13 is indefinite over the recitation of the limitations “the sealed storage pouch” and “wherein storing the sealed storage pouch comprises.” First, there is insufficient antecedent basis in the claims for the limitation “the sealed storage pouch.” While claim 1 refers to a “sealed sample pouch,” the claim does not recite a “sealed storage pouch.” Further, the recitation “wherein storing the sealed storage pouch comprises” is unclear, as claim 1 does not include a step of “storing the sealed storage

Art Unit: 1634

pouch.” Rather, claim 1 includes a step of “storing the sealed sample pouch.” As claim 1 does not include a step of “storing the sealed storage pouch,” it is unclear as to how claim 13 is intended to limit the method of claim 1. The claim should be amended so as to make clear how claim 13 relates back to and further limits the method of claim 1.

Claim 13 is indefinite over the recitation “the labeled permanent storage record folder” in step (c). While claim 13 refers to a “permanent storage folder” both in step (a) and in step (b), there is insufficient antecedent basis in the claims for the limitation “the labeled permanent storage record folder.” Clarification is required.

Claim 13 is indefinite over the recitation of the limitation “the sample affixed to the dry solid support matrix.” There is insufficient antecedent basis for this limitation in the claims, as claim 1 does not refer to a sample affixed to the dry solid support matrix.

Claim 14 is indefinite over the recitation of the limitations “the at least one specimen circles comprising the dry solid support matrix” and “the sample affixed thereto.” There is insufficient antecedent basis for these limitations in the claims. Claim 1, from which claim 14 depends, does not refer to “at least one specimen circles” or to an “affixed” sample.

Claims 15-16 are indefinite over the recitation of the following limitations for which antecedent basis is lacking:

“the dry solid support matrix” in claim 15, step (a);

“the sponge containing the sample sorbed thereon” in claim 15, step (c);

“the labeled dry solid support matrix on the storage card” in claim 15, step (c);

“the affixed sample” and “the affixed non-blood genetic material” in claim 15, step (d);

“the dry solid matrix,” “the sample affixed to the dry solid matrix,” and “the storage card containing the sample affixed to the dry solid matrix” in claim 15, step (f);

“the closed portion of the resealable storage pouch” in claim 15, step (h);

“the sealed storage pouch” and “the labeled permanent storage record folder” in claim 15, step (j); and

“the sample affixed to the dry solid support matrix” in claim 15, step (k).

The claims should be amended so as to provide antecedent basis for each of the above limitations. It is noted that suggested amendments for correction of several of these limitations are provided above (in rejections of claims dependent from claim 1).

Claim 16 is indefinite over the recitation of the limitations “the at least one specimen circles comprising the dry solid support matrix” and “the non-blood genetic material affixed thereto.” There is insufficient antecedent basis for these limitations in the claims. It is noted that step (a) of claim 15 refers to “one or more specimen circles” but not “at least one specimen circles.”

Claim 16 is also indefinite because while the claim requires the repetition of steps (a) and (b) in order to accomplish the transfer of genetic material to multiple specimen circles, steps (a) and (b) do not encompass the transfer or “blotting” of a specimen. Rather, steps (a) and (b) are drawn to labeling and swabbing, respectively; it is unclear as to how repetition of these steps would accomplish transfer to multiple specimen

Art Unit: 1634

circles. It appears that claim 16 may have been intended to require “repeating steps (b) and (c).” Clarification is required.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Quattrocchi (U.S. Patent No. 5,978,466 [11/1999]), in light of the teachings of Roget’s Interactive Thesaurus (Roget’s Interactive Thesaurus, First Edition, v 1.0.0, Lexico Publishing Group, LLC, 2003)(hereinafter referred to as “Roget”).

Quattrocchi discloses a kit comprising each of the components required by the instant claims (see entire reference, especially column 4, line 28-column 5, line 12; column 6, line 2-column 8, line 35).

Regarding the “sponge” required by claim 17, (a), Quattrocchi teaches inclusion in his kit of a “sponge pad;” it is an inherent property of such a pad that it is a type of “sponge” (specifically, a sponge in a particular shape/form)(see column 6, lines 15-29, and particularly lines 42-45).

Regarding the “dry solid support matrix” of claim 17, (b), Quattrocchi discloses inclusion in his kit of a collection card that includes “cotton fiber filter paper” designated for sample collection; it is an inherent property of such filter paper that it is a type of “dry solid support matrix” (see column 6, lines 15-29, and particularly column 7, lines 33-36).

With respect to the desiccant of claim 17, (c), Quattrocchi discloses inclusion in his kit of a “drying agent (desiccant)” (see column 6, lines 22 and 52-54).

Regarding the “storage pouch” of claim 17, (d), and claim 18, the kit taught by Quattrocchi comprises a “specimen bag” that is preferably a “clear plastic bag that can be securely closed along its upper edge” (see column 6, line 23 and column 8, lines 15-24). It is an inherent property of the specimen bag taught by Quattrocchi that it is a resealable pouch in which specimens are stored during the practice of Quattrocchi’s methods; the bag of Quattrocchi therefore constitutes a type of resealable “storage pouch.”

With respect to the “permanent storage record folder” of claim 17, (e), it is noted that a limiting definition of this term is not provided in either the specification or in the art, and that the claims are not limited, e.g., to a type of “folder” known in the art as having a particular form or structure (such as, for example, a “hanging file folder”). Quattrocchi discloses the inclusion in his kit of a “storage packet” that is preferably a “foil lined opaque envelope” (see column 6, line 22 and column 8, lines 1-15). While Quattrocchi does not employ the term “folder” in describing his “storage packet,” the packet/envelope of Quattrocchi is folded and employed in storage (see, e.g., column 8, lines 10-15). Further, Roget teaches that one well known definition of the term “folder” is “envelope” (see entire reference). Accordingly, it is an inherent property of the envelope taught by Quattrocchi that it is a type of “folder.” The instant claims do not require a folder having particular structural elements, and are not drawn to, e.g., a method in which a folder is employed in a particular manner; rather, the claims merely

require inclusion of a component that constitutes a “permanent storage record folder.” While Quattrocchi does not employ the term “permanent storage record,” Quattrocchi describes his envelope as a “storage packet,” and it is an inherent property of the envelope of Quattrocchi that it could be stored, either permanently or temporarily. Further, the recitation “permanent storage record” does not result in or require the presence in the “folder” of the claims of any particular structural or functional elements that are lacking from the envelope of Quattrocchi. Accordingly, the storage packet/envelope of Quattrocchi constitutes a type of “permanent storage record folder” meeting the limitations of the instant claims.

With respect to the “tape” of claim 19, (f), Quattrocchi discloses the inclusion in his kit of an adhesive strip (see, e.g., column 8, lines 10-15); it is an inherent property of the adhesive strip of Quattrocchi that it constitutes a type of tape. It is noted that the adhesive strip taught by Quattrocchi is incorporated into the storage packet contained in Quattrocchi’s kit (see column 8, lines 10-15). However, the instant claim merely requires the presence in the claimed kit of “tape,” the claim does not require that the tape of the kit be present in a particular form. Accordingly, the adhesive strip taught by Quattrocchi meets the limitations of the claim.

It is noted that the recitation of the intended use “for collecting non-blood genetic material” in the preamble of claim 17 does not result in a structural difference between the claimed invention and the kit taught by Quattrocchi, and further that the kit of Quattrocchi is capable of performing the intended use. Accordingly, Quattrocchi anticipates the claimed invention. (See *MPEP* 2111.02 for a further discussion of the

Art Unit: 1634

weight given to preamble statements reciting purpose or intended use of a claimed product).

10. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Quattrocchi, in light of the teachings of Roget and the teachings of Turner (U.S. Patent No. 5,211,286 [5/1993]).

It is first noted that claim 20 depends from claim 19, which depends from claim 17.

Quattrocchi discloses a kit comprising each of the components required by instant claim 20 (see entire reference, especially column 4, line 28-column 5, line 12; column 6, line 2-column 8, line 35).

Regarding the “sponge” required by claim 17, (a), Quattrocchi teaches inclusion in his kit of a “sponge pad;” it is an inherent property of such a pad that it is a type of “sponge” (specifically, a sponge in a particular shape/form)(see column 6, lines 15-29, and particularly lines 42-45).

Regarding the “dry solid support matrix” of claim 17, (b), Quattrocchi discloses inclusion in his kit of a collection card that includes “cotton fiber filter paper” designated for sample collection; it is an inherent property of such filter paper that it is a type of “dry solid support matrix” (see column 6, lines 15-29, and particularly column 7, lines 33-36).

With respect to the desiccant of claim 17, (c), Quattrocchi discloses inclusion in his kit of a “drying agent (desiccant)” (see column 6, lines 22 and 52-54).

Regarding the “storage pouch” of claim 17, (d), and claim 18, the kit taught by Quattrocchi comprises a “specimen bag” that is preferably a “clear plastic bag that can

Art Unit: 1634

be securely closed along its upper edge" (see column 6, line 23 and column 8, lines 15-24). It is an inherent property of the specimen bag taught by Quattrocchi that it is a resealable pouch in which specimens are stored during the practice of Quattrocchi's methods; the bag of Quattrocchi therefore constitutes a type of resealable "storage pouch."

With respect to the "permanent storage record folder" of claim 17, (e), it is noted that a limiting definition of this term is not provided in either the specification or in the art, and that the claims are not limited, e.g., to a type of "folder" known in the art as having a particular form or structure (such as, for example, a "hanging file folder"). Quattrocchi discloses the inclusion in his kit of a "storage packet" that is preferably a "foil lined opaque envelope" (see column 6, line 22 and column 8, lines 1-15). While Quattrocchi does not employ the term "folder" in describing his "storage packet," the packet/envelope of Quattrocchi is folded and employed in storage (see, e.g., column 8, lines 10-15). Further, Roget teaches that one well known definition of the term "folder" is "envelope" (see entire reference). Accordingly, it is an inherent property of the envelope taught by Quattrocchi that it is a type of "folder." The instant claims do not require a folder having particular structural elements, and are not drawn to, e.g., a method in which a folder is employed in a particular manner; rather, the claims merely require inclusion of a component that constitutes a "permanent storage record folder." While Quattrocchi does not employ the term "permanent storage record," Quattrocchi describes his envelope as a "storage packet," and it is an inherent property of the envelope of Quattrocchi that it could be stored, either permanently or temporarily.



Further, the recitation “permanent storage record” does not result in or require the presence in the “folder” of the claims of any particular structural or functional elements that are lacking from the envelope of Quattrocchi. Accordingly, the storage packet/envelope of Quattrocchi constitutes a type of “permanent storage record folder” meeting the limitations of the instant claim.

Claim 20 further requires the inclusion in the claimed kit of “tamper-resistant security tape.” Quattrocchi discloses the inclusion in his kit of an adhesive strip (see, e.g., column 8, lines 10-15); it is an inherent property of the adhesive strip of Quattrocchi that it constitutes a type of tape. It is noted that the adhesive strip taught by Quattrocchi is incorporated into the storage packet contained in Quattrocchi’s kit (see column 8, lines 10-15). However, the claim merely requires the presence in the claimed kit of “tamper resistant security tape;” the claim does not require that the tape of the kit be present in a particular form (e.g., separate or unattached from other kit components). Further, it is noted that a limiting definition of the term “tamper resistant security tape” is not provided in either the specification or in the art, and that the recitation “tamper resistant security” does not alter the structural or functional properties of the tape of the claim in any way that differentiates it from the tape employed by Quattrocchi. Further, Turner (U.S. Patent No. 5,211,286) discloses that the use of an “adhesive decal” to seal an envelope or container containing a biological sample will “insure against tampering” (see entire reference, particularly column 4, lines 28-42). Thus, the teachings of Turner establish that it is an inherent property of an adhesive or tape that it is “tamper resistant” and improves “security” of a sample that is, e.g., sealed in an envelope using said

adhesive/tape. Accordingly, the tape employed by Quattrocchi meets the limitations of the claim, and Quattrocchi anticipates the kit of claim 20.

It is noted that the recitation of the intended use "for collecting non-blood genetic material" in the preamble of claim 17 does not result in a structural difference between the claimed invention and the kit taught by Quattrocchi, and further that the kit of Quattrocchi is capable of performing the intended use. Accordingly, Quattrocchi anticipates the claimed invention. (See *MPEP* 2111.02 for a further discussion of the weight given to preamble statements reciting purpose or intended use of a claimed product).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1634

13. Claims 1-6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne (U.S. Patent No. 5,972,386 [10/1999]) in view of Quattrocchi (U.S. Patent No. 5,978,466 [11/1999]).

Burgoyne teaches methods for collection, storage, and analysis of nucleic acids in which biological samples containing genetic material are collected and stored on a dry solid medium (see entire reference). Burgoyne discloses that samples are to be collected by "removing the sample from a source and applying the sample" to a dry solid medium using methods "known in the art" (column 4, lines 51-59). Burgoyne teaches that the biological samples employed in his methods may be "derived from any source", and include saliva containing buccal cells (column 5, lines 5-20). It is a property of the dry solid media taught by Burgoyne that they constitute dry solid support matrices (see, e.g., column 6, lines 20-59, which describes several types of dry solid matrices that may be employed as a dry solid medium, either alone or in combination with various compositions that may be sorbed to the matrix). Thus, Burgoyne teaches steps of collecting a sample of non-blood genetic material and transferring the sample to a dry solid support matrix. Furthermore, Burgoyne discloses that samples may be preserved or analyzed immediately, teaching that nucleic acids may be released from his medium for analysis after a storage period "as short as the time necessary to transfer a sample of GM [genetic material] from a collection source to the place where subsequent analysis is to be performed", and that "Storage may be for a few seconds up to many years, preferably, about a few seconds up to 100 years" (column 5, lines 35-49). Burgoyne teaches that samples of genetic material collected and stored on dry solid

matrices may be stored under a variety of conditions (column 5, lines 35-49). For example, Burgoyne states that "The conditions under which a sample of GM may be stored on a dry solid medium of the invention is variable", that "Typically, samples are stored at temperatures from -200°C to 40°C", and that "stored samples may optionally be stored in dry or desiccated conditions or under an inert atmosphere" (column 5, lines 42-47). While Burgoyne does not explicitly refer to storage of a collected sample "in a location designated by" the individual collecting the sample or the subject from whom the sample is taken, this recitation in the claims is sufficiently broad so as to encompass storage by the practitioner of the method (i.e., the individual collecting the sample) in any of the locations or conditions disclosed by Burgoyne, as it is a property of any location in which the practitioner chooses to store the sample that this location constitutes a location "designated by the individual." For example, Burgoyne discloses that storage may occur for as little as "about a few seconds" (see column 5, lines 35-49); thus, placement of a sample-containing matrix on a laboratory bench for virtually any length of time would constitute storage "in a location designated" by the individual who collected the sample. Accordingly, Burgoyne teaches storage of a sample-containing matrix "in a location designated by the individual or the subject."

While Burgoyne teaches that his dry solid medium may be provided in the form of a card which has multiple locations for sample application (see column 17, lines 6-51), Burgoyne does not disclose the use of a dry solid support matrix "contained on a storage card," does as required by the claims (see claim 1, step (b)). Specifically, it is noted that the claim language "dry solid support matrix contained on a storage card"

limits the claims in such a way that the claims do not encompass a dry solid matrix in the shape of a card, as such a structure does not constitute a matrix "contained on" a card. Further, while Burgoyne teaches coating or encasing a sample-containing matrix in a plastic film (column 9, lines 24-45), Burgoyne does not teach sealing a sample-containing storage card in a "sample pouch," as required by the claims (see claim 1, step (c)).

Quattrocchi discloses methods for testing biological samples in which samples are self-collected, packaged and mailed to a testing site (see entire reference). Quattrocchi discloses collection of samples on a "collection card" that includes "specimen spots" composed of "special paper" for sample collection and preservation, as well as an area for recordation of information regarding a subject (see column 4, lines 57-67; column 6, line 55-column 7, line 67). Quattrocchi also teaches sealing a sample-containing collection card, along with a desiccant, in a "storage packet" which is preferably an envelope (column 5, lines 1-4; column 8, lines 1-15); it is a property of the sample-containing storage packet taught by Quattrocchi that it is a type of "sample pouch." Further, Quattrocchi discloses that a collection card and sample pouch may be employed successfully by individuals in self-collection of biological samples (see entire reference).

In view of the teachings of Quattrocchi, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Burgoyne so as to have employed therein a storage card containing the dry solid medium of Burgoyne, and so as to have sealed a sample-containing storage card

in a "sample pouch" prior to storage. First, Quattrocchi discloses that his collection card allows for the inclusion of a variety of written information, and further contains clearly marked areas for specimen collection, which areas are "outlined using black biological ink so that ink will not interfere with the specimen and an accurate test result can be obtained" (see column 4, lines 57-67; column 6, line 55-column 7, line 67; particularly column 7, lines 40-43). Accordingly, an ordinary artisan would have been motivated to have employed in Burgoyne's method a collection card containing the medium of Burgoyne, rather than Burgoyne's medium alone, in order to facilitate both the collection of samples and the collection of information regarding a subject, for the advantages of improved accuracy and convenience in collection, storage, and testing. Quattrocchi also discloses that the sealing of a sample-containing collection card in a storage packet with a desiccant (column 5, lines 1-4; column 8, lines 1-15). One of ordinary skill in the art would readily recognize that this method of storage/preservation is more convenient and less time-consuming than the application of a matrix-coating film taught by Burgoyne. Accordingly, one of ordinary skill in the art would have been motivated to have further modified the method of Burgoyne so as to have sealed a sample-containing card in a "storage pouch" for the advantages of convenience and efficiency. Finally, Quattrocchi discloses that a collection card may be employed by individuals in self-collection of biological samples, and that the sealing of a sample-containing collection card in a storage packet facilitates self-collection of a sample of genetic material and transport of that sample to a laboratory for anonymous testing (see entire reference). Accordingly, one of ordinary skill in the art would have been motivated to

have modified the method of Burgoyne so as to have employed therein a collection card and sample pouch, as discussed above, in order that the method could be practiced by either a subject (in self-collection) or by another individual, for the advantage of increased convenience and versatility.

It is noted that Quattrocchi discloses the use of his collection card in collection of blood samples, but not in collection of other types of biological samples. However, Burgoyne et al discloses that his dry solid media may be successfully employed in the collection, storage and analysis of a variety of different types of genetic material samples, including other body fluids and tissue extracts, "saliva containing buccal cells," bacterial/viral suspensions, etc. (see, e.g., column 5, lines 5-20). Accordingly, an ordinary artisan would have had a reasonable expectation of success when practicing methods of collecting and storing "a non-blood genetic material sample" using a collection card containing the dry solid media of Burgoyne.

Regarding claim 2, it is again noted that Quattrocchi discloses that a collection card and sample pouch may be employed successfully by individuals in self-collection of biological samples (see entire reference). One of ordinary skill in the art would have been motivated to have modified the method of Burgoyne so as to have employed therein a collection card and sample pouch, as discussed above, in order that the method could be practiced by either a subject (in self-collection) or by another individual, for the advantage of increased convenience and versatility.

Regarding claims 3-4, Burgoyne teaches that his dry solid media may be employed in the collection, storage and analysis of a variety of different types of genetic

Art Unit: 1634

material samples, including "saliva containing buccal cells" and suspensions of bacteria or viruses (see, e.g., column 5, lines 5-20). Further, to the extent that claim 4 may be intended to be drawn to a sample containing both saliva and/or mouth cells in combination with bacterial or viral material, Burgoyne discloses that samples of genetic material may be contaminated with pathogenic microorganisms, and teaches the inclusion in his media of compositions to effect the inactivation of such contaminants (see, e.g., column 2, lines 63-65; column 5, lines 21-29; column 7, lines 4-20).

Accordingly, Burgoyne suggests collecting and storing oral samples contaminated with bacterial and/or viral material; further, it is well known to those of ordinary skill that samples of saliva and/or buccal cells typically include some kind of bacterial and/or viral contaminants. The combined teachings of Burgoyne and Quattrocchi are sufficient to suggest the collection and storage of any type of oral biological sample, including such contaminated samples.

Regarding claim 5, Burgoyne teaches the collection of genetic material samples from both human and non-human animals (see column 5, lines 10-11).

Regarding claim 6, Burgoyne teaches dry solid media including compositions that protect genetic material samples from degradation and contamination (see, e.g., column 2, lines 63-65; column 5, lines 21-29; column 7, lines 4-20).

Regarding claim 14, Quattrocchi discloses that a collection card comprising multiple specimen areas allows for the collection of, e.g., "four different specimens" (see column 7, lines 33-52). Regarding the shape of specimen collection areas on a collection card, Quattrocchi further teaches that it is "best if the shapes are circles" (see



column 7, lines 33-52, and particularly line 43). In view of this teaching of Quattrocchi, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Burgoyne so as to have repeated steps of collecting and transferring samples to a collection card containing "specimen circles" of the dry solid medium of Burgoyne, thereby providing a sample in each circle. An ordinary artisan would have been motivated to have made such a modification in order to have provided the maximum number of samples per card for analysis, for the advantages of increased efficiency and accuracy in subsequent testing of samples.

14. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne in view of Quattrocchi, as applied to claims 1-6 and 14, above, in light of the teachings of Roget's Interactive Thesaurus (Roget's Interactive Thesaurus, First Edition, v 1.0.0, Lexico Publishing Group, LLC, 2003)(hereinafter referred to as "Roget").

Claim 13 requires that "storing the sealed storage pouch" comprises a step of "labeling a permanent storage folder," a step of "placing the sealed sample pouch into the permanent storage folder," and a step of "storing the labeled permanent storage record folder in a location designated by the individual or the subject wherein the sample affixed to the dry solid support matrix is obtainable at any time by the individual or the subject for subsequent analysis."

As discussed in paragraph 13, above, Quattrocchi discloses that a collection card may be employed by individuals in self-collection of biological samples, and that the sealing of a sample-containing collection card in a storage packet facilitates self-collection of a sample of genetic material and transport of that sample to a laboratory for

Art Unit: 1634

anonymous testing. Regarding steps of labeling a “permanent storage folder” and storing the storage packet in such a folder, Quattrocchi further discloses that to accomplish transport of a self-collected sample to a laboratory for analysis, the storage packet is placed inside an envelope (see, e.g., column 5, lines 8-11; column 8, lines 10-36). As Quattrocchi discloses that the use of a collection card, storage packet, and envelope allow a subject to collect, store, and mail a sample of their own genetic material to a laboratory for anonymous testing, one of ordinary skill in the art would have been motivated to have modified the method of Burgoyne so as to have employed therein a collection card and sample pouch, as discussed above, and further to have included a step of enclosing the storage pouch in a mailing envelope, in order to have allowed an individual to perform the method in collecting their own genetic material for anonymous testing, for the advantage of providing both convenience and confidentiality in sample collection and testing.

It is noted that Quattrocchi does not describe the envelope in which the storage packet is enclosed as a “permanent storage folder” or “permanent storage record folder.” However, a limiting definition of these terms is not provided in either the specification or in the art, and the claim is not limited, e.g., to a type of “folder” known in the art as having a particular form or structure (such as, for example, a “hanging file folder”). Further, the instant claim does not require a folder having particular structural elements; rather, the claim merely requires the use of a structure that constitutes a “permanent storage folder”/“permanent storage record folder.” Roget teaches that one well known definition of the term “folder” is “envelope” (see entire reference), and it is a

Art Unit: 1634

property of the envelope taught by Quattrocchi that it is a type of "folder" that could be stored, either permanently or temporarily. Further, the recitation "permanent storage record" does not result in or require the presence in the "folder" of the claim of any particular structural or functional elements that are lacking from the envelope of Quattrocchi. Accordingly, the envelope of Quattrocchi constitutes a type of "permanent storage folder"/"permanent storage record folder" meeting the limitations of the instant claim.

It is also noted that Quattrocchi discloses that the storage packet is to be placed inside a "specimen bag" prior to placement in the mailing envelope. However, as the instant claim recites the open transitional language "comprises," the claim is sufficiently broad so as to encompass steps of enclosing a sample pouch in any type of other enclosure or container prior to placing the pouch in a folder.

Regarding claim 13, step (a), neither Burgoyne nor Quattrocchi disclose a step of labeling a folder. However, as Quattrocchi disclose that the purpose of placing the storage packet into an envelope is to allow the packet to be mailed to a laboratory for analysis, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have written or otherwise placed both mailing and return addresses on the envelope, thereby labeling the envelope, for the advantage of assuring delivery of the envelope to the proper destination.

Regarding step (c) of claim 13, it is again noted that while Burgoyne does not explicitly refer to storage of a collected sample "in a location designated by" the individual collecting the sample or the subject from whom the sample is taken, this

recitation is sufficiently broad so as to encompass storage by the practitioner of the method in any of the locations or conditions disclosed by Burgoyne, as it is a property of any location in which the practitioner chooses to store the sample that this location constitutes a location "designated by" the practitioner. Further, Burgoyne discloses that storage may occur for as little as "about a few seconds" (see column 5, lines 35-49); thus, placement of the sample in any location by the practitioner for virtually any length of time would constitute storage "in a location designated" by the individual who collected the sample. Further, regarding the requirement that the sample be "obtainable at any time by the individual or the subject for subsequent analysis," it is noted that the recitation "obtainable at any time" is sufficiently broad so as to encompass employing any number and type of steps to accomplish "obtaining" the sample. Accordingly, the claim as written is sufficiently broad so as to encompass, e.g., "storing" an envelope containing the sample for a brief period of time (e.g., seconds, minutes, hours) prior to mailing, during which period of "storing" the sample is "obtainable" by the subject. Accordingly, the combined teachings of Burgoyne and Quattrocchi suggest all the limitations of the instant claim.

15. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne in view of Quattrocchi, as applied to claims 1-6 and 14, above, and further in view of Tess et al (*Pediatr. Infect. Dis. J.* 15(9):787-790 [9/1996]).

Regarding claims 7-8, Quattrocchi teaches labeling of a collection card having one or more specimen circles, both with identifying information regarding a subject, and with biological ink for demarcation of specimen circles (see column 6, line 55-column 7,

Art Unit: 1634

line 67). Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have labeled the collection card suggested by Burgoyne and Quattrocchi in the manner disclosed by Quattrocchi for the advantage of allowing the rapid identification of the subject and of the location of each collected specimen. However, while Burgoyne teaches that samples of genetic material collected and stored on his media may be “derived from any source” and may include, e.g., “saliva containing buccal cells” (see column 5, lines 5-20), and that samples are to be collected by methods “known in the art” (column 4, lines 49-59, particularly lines 55-56), Burgoyne and Quattrocchi do not teach a step of “swabbing the inside of the mouth of the subject with an absorbent material wherein the sample absorbs onto the absorbent material,” as required by claims 7-8, or teach the use of a sponge as said “absorbent material,” as required by claim 8. Further, regarding claim 9, while Burgoyne teaches air drying of samples applied to his dry solid media (see, e.g., column 4, line 65-column 5, line 4), Burgoyne and Quattrocchi do not teach blotting an absorbent material containing a sample onto specimen circles to affix the sample to the matrix.

Tess et al disclose a method of collecting oral fluid samples from children that comprises “rubbing a soft sponge foam swab” along the crevicular space, such that the sponge swab becomes “saturated” (see entire reference, particularly page 788, left column). Tess et al teach that this method of collection provided samples that produced accurate test results and that the method “was overwhelmingly acceptable to mothers and children” because it was familiar and painless (as compared to venipuncture for collection of blood) (p. 789). In view of the teachings of Tess et al, it would have been

Art Unit: 1634

*prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Burgoyne and Quattrocchi so as to have collected oral fluid samples using a sponge. An ordinary artisan would have been motivated to have made such a modification for the advantage of providing a rapid, painless and familiar means of collecting samples of genetic material from children, as suggested by Tess et al. Further, an ordinary artisan would have been motivated to have blotted the sample-containing sponge taught by Tess et al onto the specimen circles present on the collection card suggested by Burgoyne and Quattrocchi for the advantage of achieving rapid and simple transfer of the sample to the collection card. Tess et al discloses that sample-containing sponge swabs are "saturated" with fluid (see p. 788, left column), and further, Burgoyne discloses that genetic material samples may be derived "from any source" (column 5, lines 1-2). Accordingly, an ordinary artisan would have had a reasonable expectation of success in affixing an oral swab sample to Burgoyne's dry solid medium by means of blotting onto a specimen circle a sponge swab sample obtained as described by Tess et al.

16. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne in view of Quattrocchi, as applied to claims 1-6 and 14, above, and further in view of Haas et al (U.S. Patent No. 5,862,101 [1/1999]).

First, regarding the requirement of claim 10, step (a), for a step of "labeling the storage pouch," it is again noted that Quattrocchi discloses that a collection card may be employed by individuals in self-collection of biological samples, and that the sealing of a sample-containing collection card in a storage packet facilitates self-collection of a

Art Unit: 1634

sample of genetic material and transport of that sample to a laboratory for anonymous testing (see entire reference). As discussed above, one of ordinary skill in the art would have been motivated to have modified the method of Burgoyne so as to have employed therein a collection card and sample pouch in order that the method could be practiced by either a subject (in self-collection) or by another individual, for the advantage of increased convenience and versatility. Further, while Quattrocchi does not disclose labeling his "storage packet," Quattrocchi does disclose that in methods requiring self-collection and transport of samples to a laboratory, a variety of containers, such as multiple types of envelopes and multiple types of plastic bags, may be employed in packaging and transport (see, e.g., column 8, lines 1-35). As a subject performing self-collection of a biological sample would be relatively unfamiliar with these various containers and materials, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have labeled the storage pouch intended to hold the collection card and desiccant, for the advantage of insuring that the card and desiccant are placed in the correct receptacle prior to further packaging and shipment.

Regarding steps (b)-(c) of claim 10, as discussed above, the combined references of Burgoyne and Quattrocchi suggest steps of placing a sample-containing collection card in a storage pouch with a desiccant and closing and sealing the pouch (see Quattrocchi, column 8, lines 1-15). Regarding claim 11, it is noted that the storage packet taught by Quattrocchi is "resealable," as it is a property of the packet that it may be resealed after opening using the adhesive tape supplied thereon. However, as the

Art Unit: 1634

tape taught by Quattrocchi is incorporated into the storage packet such that it is internal upon closure of the packet (see column 8, lines 10-15), Burgoyne and Quattrocchi do not teach a step of "placing a tape over the closed portion of the storage pouch."

Further, while it is a property of any type of tape that it impedes tampering and increases security of a stored sample, Burgoyne and Quattrocchi do not teaching placing "tamper resistant security" tape "over the closed portion of the storage pouch," as required by claim 12.

Haas et al disclose a particular type of "tamper indicating packaging tape" that includes a pattern and allows one to determine that a item sealed with said tape has been tampered with by visual inspection of the tape (see entire reference, particularly column 6, lines 22-26; column 8, lines 34-40; column 16, line 45-column 17, line 19; Figures 29-31). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Burgoyne and Quattrocchi so as to have sealed the storage packet containing the collection card and desiccant by placing the tape of Haas et al "over the closed portion of the storage pouch," either in addition to, or instead of, employing the adhesive tape disclosed by Quattrocchi. An ordinary artisan would have been motivated to have made such a modification in order to have allowed for rapid, visual detection of any possible tampering that may have occurred subsequent to the closure of the storage pouch, for the advantage of rapidly determining whether a sample has been disturbed, potentially contaminated or otherwise altered since collection.



Art Unit: 1634

17. Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne in view of Quattrocchi, as applied to claims 1-6 and 14, above, and further in view of Biddle et al (U.S. Patent No. 5,492,268 [2/1996]).

This rejection applies to the claim to the extent that it may be limited to methods in which a particular type of "permanent storage folder" or "permanent storage record folder" is employed, specifically, a file folder having a structure that is specifically designed for the storage of permanent information and records. Burgoyne and Quattrocchi do not teach the placement of a sample contained in a sealed pouch into such a folder, and further do not teach labeling such a folder. Biddle et al teach a multi-section folder having structures designed for the permanent attachment and inclusion of permanent information and data, as well as the temporary attachment and inclusion of temporary information and data (see entire reference, particularly column 2, lines 2-22). Biddle et al disclose that such a folder meets a need to "transfer and update temporary information while at the same time preserving, organizing, maintaining, and accessing permanent information," and that such a folder is "quick and easy to use, easy to understand" and portable (see column 1, lines 59-65). In view of the teachings of Biddle et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Burgoyne and Quattrocchi so as to have placed and stored the sealed storage packet inside such a folder. An ordinary artisan would have been motivated to have made such a modification in order to have stored the contents of the sealed storage packet within a folder that contains and/or allows for the inclusion therein of additional information (both temporary and

Art Unit: 1634

permanent) regarding the subject, thereby facilitating the consolidation of a variety of information regarding the subject within a portable structure that allows for rapid and easy access to that information, for the advantages of convenience and efficiency.

Biddle et al also teach that tabs within their folder are to be labeled, either with words or numbers, thereby allowing for the identification of the information contained within each folder section (see, e.g., column 5, lines 50-64). Accordingly, regarding the labeling step (a) of claim 13, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have labeled the folder as described by Biddle et al prior to storage of the sample pouch therein for the advantage of allowing for the rapid identification of the information contained therein by a user of the folder.

Regarding step (c) of claim 13, it is again noted that while Burgoyne does not explicitly refer to storage of a collected sample "in a location designated by" the individual collecting the sample or the subject from whom the sample is taken, this recitation is sufficiently broad so as to encompass storage by the practitioner of the method in any of the locations or conditions disclosed by Burgoyne, as it is a property of any location in which the practitioner chooses to store the sample that this location constitutes a location "designated by" the practitioner. Further, Burgoyne discloses that storage may occur for as little as "about a few seconds" (see column 5, lines 35-49); thus, placement of the sample in any location by the practitioner for virtually any length of time would constitute storage "in a location designated" by the individual who collected the sample. Further, regarding the requirement that the sample be "obtainable at any time by the individual or the subject for subsequent analysis," it is noted that the

Art Unit: 1634

recitation "obtainable at any time" is sufficiently broad so as to encompass employing any number and type of steps to accomplish "obtaining" the sample. Accordingly, the claim as written is sufficiently broad so as to encompass, e.g., "storing" a file folder containing the sample for a brief period of time (e.g., seconds, minutes, hours), during which period of "storing" the sample is "obtainable" by the subject.

18. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne in view of Quattrocchi and Tess et al, as applied to claims 7-9, above, and further in view of Haas et al, in light of Roget.

As discussed in paragraphs 13 and 15, above, Burgoyne, Quattrocchi and Tess et al suggest a method including steps of labeling as in claim 15, step (a), swabbing as in claim 15, step (b), blotting as in claim 15, step (c), air drying as in claim 15, step (d) (as well as a dry solid support matrix meeting the requirements of claim 15, step (d)), placing a collection card in a resealable storage pouch with a desiccant as in claim 15, step (f), closing the pouch as in claim 15, step (g), and repeating method steps "until all of the at least one specimen circles" contain genetic material, as in dependent claim 16.

Regarding the requirement of claim 15, step (e), for a step of "labeling a resealable storage pouch," it is again noted that Quattrocchi discloses that a collection card may be employed by individuals in self-collection of biological samples, and that the sealing of a sample-containing collection card in a storage packet facilitates self-collection of a sample of genetic material and transport of that sample to a laboratory for anonymous testing (see entire reference). The storage packet taught by Quattrocchi is "resealable," as it is a property of the packet that it may be resealed after opening using

Art Unit: 1634

the adhesive tape supplied thereon (see column 8, lines 10-15). As discussed above, one of ordinary skill in the art would have been motivated to have modified the method of Burgoyne so as to have employed therein a collection card and sample pouch in order that the method could be practiced by either a subject (in self-collection) or by another individual, for the advantage of increased convenience and versatility. Further, while Quattrocchi does not disclose labeling his "storage packet," Quattrocchi does disclose that in methods requiring self-collection and transport of samples to a laboratory, a variety of containers, such as multiple types of envelopes and multiple types of plastic bags, may be employed in packaging and transport (see, e.g., column 8, lines 1-35). As a subject performing self-collection of a biological sample would be relatively unfamiliar with these various containers and materials, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have labeled the storage pouch intended to hold the collection card and desiccant, for the advantage of insuring that the card and desiccant are placed in the correct receptacle prior to further packaging and shipment.

Regarding the steps of labeling a "permanent storage record folder" of claim 15, step (i), and placing and storing the storage packet in such a folder, as in claim 15, steps (j)-(k), Quattrocchi further discloses that to accomplish transport of a self-collected sample to a laboratory for analysis, the storage packet is placed inside an envelope (see, e.g., column 5, lines 8-11; column 8, lines 10-36). It is noted that Quattrocchi does not describe the envelope in which the storage packet is enclosed as a "permanent storage record folder." However, a limiting definition of this term is not

Art Unit: 1634

provided in either the specification or in the art, and the claim is not limited, e.g., to a type of “folder” known in the art as having a particular form or structure (such as, for example, a “hanging file folder”). Further, the instant claim does not require a folder having particular structural elements; rather, the claim merely requires the use of a structure that constitutes a “permanent storage record folder.” Roget teaches that one well known definition of the term “folder” is “envelope” (see entire reference), and it is a property of the envelope taught by Quattrocchi that it is a type of “folder” that could be stored, either permanently or temporarily. Further, the recitation “permanent storage record” does not result in or require the presence in the “folder” of the claim of any particular structural or functional elements that are lacking from the envelope of Quattrocchi. Accordingly, the envelope of Quattrocchi constitutes a type of “permanent storage record folder” meeting the limitations of the instant claim.

It is also noted that Quattrocchi discloses that the storage packet is to be placed inside a “specimen bag” prior to placement in the mailing envelope. However, as the instant claim recites the open transitional language “comprises,” the claim is sufficiently broad so as to encompass steps of enclosing a sample pouch in any type of other enclosure or container prior to placing the pouch in a folder.

None of Burgoyne, Quattrocchi or Tess et al disclose a step of labeling a folder. However, as Quattrocchi disclose that the purpose of placing the storage packet into an envelope is to allow the packet to be mailed to a laboratory for analysis, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have written or otherwise placed both mailing and return addresses on the

Art Unit: 1634

envelope, thereby labeling the envelope, for the advantage of assuring delivery of the envelope to the proper destination.

Regarding step (k) of claim 15, it is again noted that while Burgoyne does not explicitly refer to storage of a collected sample "in a location designated by" the individual collecting the sample or the subject from whom the sample is taken, this recitation is sufficiently broad so as to encompass storage by the practitioner of the method in any of the locations or conditions disclosed by Burgoyne, as it is a property of any location in which the practitioner chooses to store the sample that this location constitutes a location "designated by" the practitioner. Further, Burgoyne discloses that storage may occur for as little as "about a few seconds" (see column 5, lines 35-49); thus, placement of the sample in any location by the practitioner for virtually any length of time would constitute storage "in a location designated" by the individual who collected the sample. Further, regarding the requirement that the sample be "obtainable at any time by the individual or the subject for subsequent analysis," the recitation "obtainable at any time" is sufficiently broad so as to encompass employing any number and type of steps to accomplish "obtaining" the sample. Accordingly, the claims as written are sufficiently broad so as to encompass, e.g., "storing" an envelope containing the sample for a brief period of time (e.g., seconds, minutes, hours) prior to mailing, during which period of "storing" the sample is "obtainable" by the subject.

Regarding step (h) of claim 15, it is a property of any type of tape that it impedes tampering and increases security of a stored sample. However, as the tape taught by Quattrocchi is incorporated into the storage packet such that it is internal upon closure

Art Unit: 1634

of the packet (see column 8, lines 10-15), Burgoyne, Quattrocchi and Tess et al do not teach a step of "placing a tamper-resistant security tape over the closed portion of the resealable storage pouch," as required by the claims.

Haas et al disclose a particular type of "tamper indicating packaging tape" that includes a pattern and allows one to determine that a item sealed with said tape has been tampered with by visual inspection of the tape (see entire reference, particularly column 6, lines 22-26; column 8, lines 34-40; column 16, line 45-column 17, line 19; Figures 29-31). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Burgoyne, Quattrocchi and Tess et al so as to have sealed the storage packet containing the collection card and desiccant by placing the tape of Haas et al "over the closed portion" of the pouch. An ordinary artisan would have been motivated to have made such a modification in order to have allowed for rapid, visual detection of any possible tampering that may have occurred subsequent to the closure of the storage pouch, for the advantage of rapidly determining whether a sample has been disturbed, potentially contaminated or otherwise altered since collection.

19. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgoyne in view of Quattrocchi and Tess et al, as applied to claims 7-9, above, and further in view of Haas et al and Biddle et al.

This rejection applies to claims 15-16 to the extent that they may be limited to methods in which a particular type of "permanent storage folder" or "permanent storage record folder" is employed in steps (i)-(k), specifically, a file folder having a structure that

Art Unit: 1634

is specifically designed for the storage of permanent information and records. This rejection applies to claims 17-20 to the extent that those claims may be limited to a particular kit that requires a sponge in the form of a swab, a type of "tamper resistant security tape" that includes a pattern and allows one to determine that a item sealed with said tape has been tampered with by visual inspection of the tape, and a type of "permanent storage record folder" that is a file folder having a structure that is specifically designed for the storage of permanent information and records.

As discussed in paragraphs 13 and 15, above, Burgoyne, Quattrocchi and Tess et al suggest a method including steps of labeling as in claim 15, step (a), swabbing as in claim 15, step (b), blotting as in claim 15, step (c), air drying as in claim 15, step (d) (as well as a dry solid support matrix meeting the requirements of claim 15, step (d)), placing a collection card in a resealable storage pouch with a desiccant as in claim 15, step (f), closing the pouch as in claim 15, step (g), and repeating method steps "until all of the at least one specimen circles" contain genetic material, as in dependent claim 16.

Regarding the requirement of claim 15, step (e), for a step of "labeling a resealable storage pouch," it is again noted that Quattrocchi discloses that a collection card may be employed by individuals in self-collection of biological samples, and that the sealing of a sample-containing collection card in a storage packet facilitates self-collection of a sample of genetic material and transport of that sample to a laboratory for anonymous testing (see entire reference). The storage packet taught by Quattrocchi is "resealable," as it is a property of the packet that it may be resealed after opening using the adhesive tape supplied thereon (see column 8, lines 10-15). As discussed above,



Art Unit: 1634

one of ordinary skill in the art would have been motivated to have modified the method of Burgoyne so as to have employed therein a collection card and sample pouch in order that the method could be practiced by either a subject (in self-collection) or by another individual, for the advantage of increased convenience and versatility. Further, while Quattrocchi does not disclose labeling his "storage packet," Quattrocchi does disclose that in methods requiring self-collection and transport of samples to a laboratory, a variety of containers, such as multiple types of envelopes and multiple types of plastic bags, may be employed in packaging and transport (see, e.g., column 8, lines 1-35). As a subject performing self-collection of a biological sample would be relatively unfamiliar with these various containers and materials, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have labeled the storage pouch intended to hold the collection card and desiccant, for the advantage of insuring that the card and desiccant are placed in the correct receptacle prior to further packaging and shipment.

Regarding step (h) of claim 15, it is noted that it is a property of any type of tape that it impedes tampering and increases security of a stored sample. However, as the tape taught by Quattrocchi is incorporated into the storage packet such that it is internal upon closure of the packet (see column 8, lines 10-15), Burgoyne, Quattrocchi and Tess et al do not teach a step of "placing a tamper-resistant security tape over the closed portion of the resealable storage pouch," as required by the claims.

Haas et al disclose a particular type of "tamper indicating packaging tape" that includes a pattern and allows one to determine that a item sealed with said tape has

Art Unit: 1634

been tampered with by visual inspection of the tape (see entire reference, particularly column 6, lines 22-26; column 8, lines 34-40; column 16, line 45-column 17, line 19; Figures 29-31). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Burgoyne, Quattrocchi and Tess et al so as to have sealed the storage packet containing the collection card and desiccant by placing the tape of Haas et al "over the closed portion" of the pouch. An ordinary artisan would have been motivated to have made such a modification in order to have allowed for rapid, visual detection of any possible tampering that may have occurred subsequent to the closure of the storage pouch, for the advantage of rapidly determining whether a sample has been disturbed, potentially contaminated or otherwise altered since collection.

Regarding the steps of labeling a "permanent storage record folder" of claim 15, step (i), and placing and storing the storage packet in such a folder, as in claim 15, steps (j)-(k), Burgoyne, Quattrocchi, Tess et al and Haas et al do not teach the placement of a sample contained in a sealed pouch into a file folder having a structure that is specifically designed for the storage of permanent information and records, and further do not teach labeling such a folder. Biddle et al teach a multi-section folder having structures designed for the permanent attachment and inclusion of permanent information and data, as well as the temporary attachment and inclusion of temporary information and data (see entire reference, particularly column 2, lines 2-22). Biddle et al disclose that such a folder meets a need to "transfer and update temporary information while at the same time preserving, organizing, maintaining, and accessing

permanent information," and that such a folder is "quick and easy to use, easy to understand" and portable (see column 1, lines 59-65). In view of the teachings of Biddle et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Burgoyne, Quattrocchi, Tess et al and Haas et al so as to have placed and stored the sealed storage packet inside such a folder. An ordinary artisan would have been motivated to have made such a modification in order to have stored the contents of the sealed storage packet within a folder that contains and/or allows for the inclusion therein of additional information (both temporary and permanent) regarding the subject, thereby facilitating the consolidation of a variety of information regarding the subject within a portable structure that allows for rapid and easy access to that information, for the advantages of convenience and efficiency. Biddle et al also teach that tabs within their folder are to be labeled, either with words or numbers, thereby allowing for the identification of the information contained within each folder section (see, e.g., column 5, lines 50-64). Accordingly, regarding the labeling step (i) of claim 15, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have labeled the folder as described by Biddle et al prior to storage of the sample pouch therein for the advantage of allowing for the rapid identification of the information contained therein by a user of the folder.

Regarding step (k) of claim 15, it is again noted that while Burgoyne does not explicitly refer to storage of a collected sample "in a location designated by" the individual collecting the sample or the subject from whom the sample is taken, this

recitation is sufficiently broad so as to encompass storage by the practitioner of the method in any of the locations or conditions disclosed by Burgoyne, as it is a property of any location in which the practitioner chooses to store the sample that this location constitutes a location "designated by" the practitioner. Further, Burgoyne discloses that storage may occur for as little as "about a few seconds" (see column 5, lines 35-49); thus, placement of the sample in any location by the practitioner for virtually any length of time would constitute storage "in a location designated" by the individual who collected the sample. Further, regarding the requirement that the sample be "obtainable at any time by the individual or the subject for subsequent analysis," it is noted that the recitation "obtainable at any time" is sufficiently broad so as to encompass employing any number and type of steps to accomplish "obtaining" the sample. Accordingly, the claims as written are sufficiently broad so as to encompass, e.g., "storing" a file folder containing the sample for a brief period of time (e.g., seconds, minutes, hours), during which period of "storing" the sample is "obtainable" by the subject.

It is again noted that this rejection applies to claims 17-20 to the extent that those claims may be limited to a particular kit that requires a sponge in the form of a swab, a type of "tamper resistant security tape" that includes a pattern and allows one to determine that a item sealed with said tape has been tampered with by visual inspection of the tape, and a type of "permanent storage record folder" that is a file folder having a structure that is specifically designed for the storage of permanent information and records. The combined teachings of Burgoyne, Quattrocchi, Tess et al, Haas et al, and Biddle et al suggest a method for collecting and storing non-blood genetic material that

employs a sponge swab (as taught by Tess et al), a resealable storage pouch in which a desiccant and a collection card including a dry solid support matrix are stored (as suggested by Burgoyne and Quattrocchi), a file folder having a structure that is specifically designed for the storage of permanent information and records (as taught by Biddle et al), and a type of tamper resistant security tape that includes a pattern and allows one to determine that a item sealed with said tape has been tampered with by visual inspection of the tape (as taught by Haas et al). Burgoyne and Quattrocchi each teach the packaging of materials for use in collecting samples of genetic material into kits (see, e.g., Burgoyne, column 17, line 57-column 18, line 60; Quattrocchi column 4, lines 29-40). Burgoyne teaches that kits “for applying, storing or processing a sample” of genetic material are advantageous for numerous reasons, including “increased safety to human sample handlers during placement of a sample onto a dry solid medium, decreased human labor costs in applying a sample to the dry solid medium, and decreased chance of sample contamination during handling” (see column 18, lines 33-37; see also column 17, lines 57-58). Quattrocchi teaches that the provision of all the reagents necessary for self-collection of genetic material in kit form allow for a specimen to be collected anonymously and “in private” (column 4, lines 29-40). In view of the teachings of Burgoyne and/or Quattrocchi, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have packaged into kits the reagents required to perform the method suggested by Burgoyne, Quattrocchi, Tess et al, Haas et al, and Biddle et al. An ordinary artisan would have been motivated to have made such a modification for the advantages of increased safety, decreased

Art Unit: 1634

risk of contamination, and cost-effectiveness, as suggested by Burgoyne and/or for the advantages of allowing for private, anonymous collection of samples by a subject, as suggested by Quattrocchi.

### ***Conclusion***

20. It is noted that instant claims 1-16 are sufficiently broad so as to encompass methods in which a non-human animal performs sample collection. However, one of skill in the art could readily determine, without undue experimentation, which embodiments encompassed by the claims are inoperative. Accordingly, one of skill in the art could make and use the claimed invention without undue experimentation. (See *MPEP* 2164.08(b) for further discussion of enablement of claims that encompass inoperative subject matter).


21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Application/Control Number: 10/034,292  
Art Unit: 1634

Page 46

A handwritten signature in black ink, appearing to read "Diana B. Johannsen". The signature is fluid and cursive, with a large, stylized initial "D" and a long, sweeping horizontal stroke at the end.

Diana B. Johannsen  
February 9, 2003